



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

**FEE**

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

DP BAR CODE NO.: 422513  
PC Code: 128825  
FOOD Use: Yes

EPA File Symbol NO.: 89118-E  
ACTION CODE: R320

DECISION NO.: 491988

DATE OUT: March 16, 2015

SUBJECT: End Use Product Chemistry Review  
Product Name: VCP-03

FROM: Hari Mukhoty, MSc, PhD.  
Product Chemistry Team  
CITAB / Registration Division (7505P)

*[Handwritten signature]*

*SRBm 03/17/15*

TO: BeWanda Alexander, RMR / Richard Gebken, RM 10  
Invertebrate and Vertebrate Branch 2 / Registration Division (7505P)

Company Name: Vive Crop Protection, Inc.  
Formulation Type: Not Provided

**INTRODUCTION:**

The registrant has submitted one basic CSF (Dated: 05/28/2014), twelve alternate formulations (Alt. A through L, Dated: 05/28/2014) and proposed a product specific label for the registration of the aforesaid product under EPA File Symbol No: 89118-E. The product chemistry data have been submitted under MRIDs: 493901-01 & -02 and a data matrix dated May 15, 2014.

CITAB has been requested to review the product chemistry data required for registration of the proposed basic and alternate formulations.

**SUMMARY OF FINDINGS:**

1. Name of Active Ingredient(s): Bifenthrin (19.3%).
2. Has the registrant claimed substantial similarity to registered product?  
[ ] Yes [ ] No [ X ] NA If yes: EPA Reg. No.
3. The source material of the active ingredient is registered with the Agency [Yes].
4. All inert ingredients have been screened by Inert Team on 06/12/2014 and have been approved for food use.

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5. Confidential Statement of Formula(s):

☒ Basic - Dated: 05/28/2014 Re-submitted: NA  
☒ Alternate - Dated: 05/28/2014 Re-submitted: NA

Alternate CSF(s) complies with 40CFR §152.43: ☒ Yes ☐ No NA ☐

6. Product label

a. Ingredient statement: Nominal concentrations of AI listed on CSF(s) concur with product label (PR Notice 91-2).

☒ Yes

Is the sub statement in compliance with PR Notice 97-6?

☒ Yes ☐ No - Uses the term "Other Ingredients"  
, if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA  
Soluble arsenic: ☐ Yes ☒ NA  
Isomeric ratios: ☒ Yes ☐ NA Cis isomers 97% minimum, trans isomers 3% maximum  
Acid equivalent: ☐ Yes ☒ NA

b. Health related sub statements:

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA  
Methanol at > 4%: ☐ Yes ☐ No ☒ NA  
Sodium Nitrate / Sodium Nitrite ☐ Yes ☐ No ☒ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Total Release Fogger PR Notice 98-6 (40 CFR 156.78 d): ☐ Yes ☐ No ☒ NA

d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No The proposed label contains detail disposal instructions.

Final decision of overall label acceptance will be made by the PM.



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7. Group A: Product Chemistry Data

CITAB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	493901-01
830.1600	Description of materials used to produce the product		X		A	"
830.1650	Description of formulation process		X		A	"
830.1670	Discussion on the formation of impurities		X		A	"
830.1700	Preliminary analysis #		NR		NR	
830.1750	Certified limits (158.350)	Standard certified limits	X		A	Standard C.L. CL. Described in proposed CSFs Dated: 05/28/2014
		Proposed Limits				
		Justification for wider limits			A	
830.1800	Enforcement analytical method #		X		A	493901-01

A = Acceptance, NR = Not Required, G = Data Gap, N = Not Acceptable, U = Upgradable  
W = Waiver Request, I = In Progress, NA = Not Applicable

# Analytical Method: Analysis was performed by HPLC method using UV detector set at 250 nm. Validation data were provided for determination of nominal concentration of active ingredients of the end-use product for precision, linearity and accuracy.

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8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Aqueous suspension	Acceptable	493901-02
830.6314	Oxidation/reduction	No chemical incompatibility / No change in color / No significant change in temp. increase.	"	"
830.6315	Flammability	Water based liquid / Not flammable	"	Data Matrix
830.6316	Explosibility	Does not contain any explosive ingredient	"	Data Matrix
830.6317	Storage stability	In progress: 1 year study (0,3,6,9,12 intervals)	"	"
830.6310	Miscibility	Not to be emulsified with oil or petroleum solvent	Acceptable	Data Matrix
830.6320	Corrosion characteristics	In progress: one year study (0,3,6,9 & 12 months intervals)	"	"
830.7000	pH	7.24	Acceptable	493901-02
830.7100	Viscosity	55.1 to 1472.0 Centistokes @ 20° C 46.7 to 1248.0 cP @40° C	"	"
830.7300	Density	0.88 g/ml	"	"

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**CONCLUSIONS:**

1. CITAB has reviewed the CSFs for the proposed basic and alternate formulations (Dated: 05/28/2014) and has found them to be acceptable. The CSFs are attached with this review and can be located in OPPIN CHEM DOCS.

2. Product chemistry Group A and Group B data are acceptable.

3. The proposed label was screened as it pertains to the product chemistry requirements. The PM should get the "Formulation Type" from the registrant. The preferred site of insertion of Formulation Type would be on the proposed label under "Direction to Use". The final review of the proposed label and uses are the purview of the PM team.